

Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: <https://reachmd.com/programs/clinicians-roundtable/reducing-barriers-to-pah-clinical-trial-participation/84959/>

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Reducing Barriers to PAH Clinical Trial Participation

Announcer:

Welcome to *Clinician's Roundtable* on ReachMD. Today, Dr. John Kingrey will share his insights on broadening representation in pulmonary arterial hypertension, or PAH, trials. He's the Director of the Pulmonary Hypertension Center at INTEGRIS Health in Oklahoma City. Let's hear from Dr. Kingrey now.

Dr. Kingrey:

I think the single most important factor, in my opinion, to having clinical trials and/or other research endeavors be more reflective of a real-world population is that we have to eliminate some of the regulation that we are under in research.

There is so much that goes into these clinical trials, and some of the regulation can happen from the sponsor: making the number of visits less cumbersome, making the requirements of where testing can be done. And I know we need it to be accurate, and we want the data to be real, but many times, I just know that there is no way that a patient sitting in front of me is going to be able to navigate the complexities of a research trial or have the time. Maybe they're working, right? And research trials don't generally operate—not our research trials—on the weekend.

We have to make them simpler. We would like to be able to capture all sorts of endpoints and all sorts of data points, but I think we have to focus on the ones that are most important and simplify the process. We have to be able to take someone who is an African American who might be disadvantaged, or a Native American, or perhaps a patient who is using drugs or addicted to methamphetamine. We have to make it easier for them to participate.

Some of this might be able to be accomplished through remote monitoring, remote data capture, and arming the research subjects with technology that they would need to do that. And I say this, but of course, none of this is simple. All of these things have been talked about. But I've been hearing in our disease state for many years that we have a problem with reflecting the real-world population, and that there are certain people that just aren't being captured. And everybody knows it, everybody's sensitive to it, and everybody wants it to be different. But the bottom line is that, with the trial design and the information that is needed, I feel like we are largely ending up in the same areas.

We've had plenty of new clinical trials. And when we get briefed, we have people come and do site visits to introduce the trial and get us ready to enroll patients. But there isn't a section on, "Hey, we need to make sure that we're capturing this percentage of X disadvantaged population or X underrepresented population." The focus is on getting people enrolled, and whether they're male, female, Black, White, or anywhere in between becomes secondary, because we just need to get people enrolled. And I understand that.

But if we're actually going to move the needle, we're going to have to have some different requirements. And for drug companies in particular, I think that what will be needed there is more time. And that flies in the face of what any of them understandably want to do. I think the other alternative is that there would be more resources dedicated by study sponsors to identify patients at certain sites and make sure that there's a dedicated effort to reach out to the underrepresented population.

Announcer:

You just heard Dr. John Kingrey discussing ways to reduce barriers to PAH clinical trial participation. To access this and other episodes in our series, visit *Clinician's Roundtable* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!